K103539

Title:	**510(k) SUMMARY** **Quanta System DUOLITE**
Submitter:	Quanta System SpA via IV Novembre,116 21058 Solbiate Olona VA / Italy
Contact:	Dr. Maurizio Bianchi QA and Regulatory Affairs Manager
Date Prepared:	February 28, 2013
Device Trade Name:	Quanta System DUOLITE
Common Name:	Laser surgical instrument for use in general surgery and Dermatology
Classification Name:	Instrument, surgical, powered, laser
Predicate Devices:	Cynosure, Inc Affinity QS Q-Switched Nd:YAG Laser System **(K050382);**
Intended Use / Indications for use:	**Nd:YAG (1064nm):** The DUOLITE Q-Switched laser is intended for treatment of vascular lesions, pigmented lesions, and for hair removal and the incision, excision, ablation, vaporization of soft tissue for general dermatology. The DUOLITE Q-Switched laser is intended for tattoo removal (blue, black and green tattoo) **Nd:YAG (532nm):** The DUOLITE Q-Switched laser is intended for treatment of vascular lesions, pigmented lesions, and for hair removal and the incision, excision, ablation, vaporization of soft tissue for general dermatology. The DUOLITE Q-Switched laser is intended for tattoo removal (red, violet, orange, yellow and brown tattoo)
Technological Characteristics:	The device includes a Q-Switched Nd:YAG laser source with 900mJ max energy at 1064 nm and 450mJ max energy at 532 nm wavelengths. The optical delivery system for the two wavelengths is the articulated arm. In addition, the DUOLITE includes a power supply; a cooling system; an optical delivery system; a microprocessor based controller; and safety features to ensure use of the appropriate laser, wavelength and hand piece.
Performance data:	None
Substantial Equivalence:	The Quanta System DUOLITE is as safe and effective as the predicate devices. The DUOLITE has the same intended uses and similar indications, technological characteristics,

and principles of operation as its predicate device as demonstrated in the table below.

	Wavelength [nm]	pulse width [ns]	Fluence [J/cm^2]	spot size (mm)	Rep. rate [Hz]
QUANTA SYSTEM DUOLITE	1064 nm	6 ns	28J/cm^2 at 2mm 12J/cm^2 at 3mm 3J/cm^2 at 6mm	2,3 and 6mm	1,2,5 and 10Hz
	532 nm	6 ns	14J/cm^2 at 2mm 6J/cm^2 at 3mm 1,5J/cm^2 at 6mm	2,3 and 6mm	1,2,5 and 10Hz
CYNOSURE AFFINITY QS (K050382)	1064 nm	6 ns	28J/cm^2 at 2mm 12J/cm^2 at 3mm 7J/cm^2 at 4mm 3J/cm^2 at 6mm	2,3,4 and 6mm	1,2,5 and 10Hz
	532 nm	6 ns	14J/cm^2 at 2mm 6J/cm^2 at 3mm 3J/cm^2 at 4mm 1,5J/cm^2 at 6mm	2,3,4 and 6mm	1,2,5 and 10Hz

The tip of the handpiece of the DUOLITE is made of Biocompatible material as the predicate device. This Sterilization method is the same as its predicate device. The Minor technological differences between the DUOLITE and its predicate devices raise no new issue of safety or effectiveness. Thus, the DUOLITE is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Quanta System, S.P.A.
% Regulatory Technology Services, LLC
Mr. Mark Job
1394 25th Street, Northwest
Buffalo, Minnesota 55313

March 15, 2013

Re: K103539
Trade/Device Name: DUOLITE
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: January 06, 2011
Received: January 07, 2011

Dear Mr. Job:

This Letter corrects our substantially equivalent letter of January 20, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,
FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): ____K103539_____

Device Name: **DUOLITE**

Indications for use:

Nd:YAG (1064nm):

The DUOLITE Q-Switched laser is intended for treatment of vascular lesions, pigmented lesions, and for hair removal and the incision, excision, ablation, vaporization of soft tissue for general dermatology. The DUOLITE Q-Switched laser is intended for tattoo removal (blue, black and green tattoo)

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Neil R Ogden -S
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(Division Sign Off) for MXM
Division of Surgical, Orthopedic,
And Restorative Devices

510(k) Number K103539

Prescription Use __X___ AND/OR Over-The-Counter Use___
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)